XPS®
Model 3000 System

Service Manual

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NOTICE

THIS MANUAL IS PROVIDED PRIMARILY FOR INFORMATION PURPOSES. ALTHOUGH THERE ARE CERTAIN TROUBLESHOOTING ACTIONS THAT MAY BE ATTEMPTED BY THE CUSTOMERE AS SPECIFICALLY LISTED IN THIS MANUAL, THE MAJORITY OF REPAIRS MUST BE UNDERTAKEN BY MEDTRONIC XOMED OR ITS AUTHORIZED REPRESENTATIVE IT OTHERWISE BEING UNSAFE TO MAINTAIN OR REPAIR THIS DEVICE.

SYMBOLS

	ATTENTION, SEE INSTRUCTIONS FOR USE
REF	CATALOG NUMBER
SN	SERIAL NUMBER
	DATE OF MANUFACTURE
	LOT NUMBER
	OFF
	ON
	REVERSE
	FORWARD
	OSCILLATION
	FOOTSWITCH — VARIABLE MODE
	FOOTSWITCH — NORMAL MODE
	FOOTSWITCH
	TYPE B APPLIED PART
ACC	ACCESSORY CONNECTOR
	MANUAL START/STOP
	HANDPIECE
	SKEETER HANDPIECE
	IRRIGANT
	COOLANT
	PUMP
MENU	MENU
	CAUTION: PINCH HAZARD. KEEP FINGERS CLEAR OF ROLLERS.

WARNINGS AND PRECAUTIONS

IT IS IMPORTANT THAT THE XPS MODEL 3000 OPERATOR BE FAMILIAR WITH THIS MANUAL: ITS PRECAUTIONS, PROCEDURES AND SAFETY ISSUES. THREE LABELS ARE USED IN THIS MANUAL TO IDENTIFY IMPORTANT CONCERNS, CONDITIONS, OR PROCEDURES:

"WARNING"

- Identifies conditions or practices that present a risk of injury to the patient and/or user.

" CAUTION / PRECAUTIONS"

- Identifies conditions or practices that could result in damage to the equipment.

"NOTE"

- Identifies special information and/or to clarify/emphasize important instructions.

WARNINGS

- DO NOT operate the XPS Model 3000 in the presence of flammable anesthetics.
- DO NOT use burs above the speed indicated on the bur label.
- Use adequate irrigation. The use of a bur without irrigation may cause an inordinate amount of heat buildup resulting in thermal injury to tissue.
- Always keep the cutting tip away from fingers and loose clothing.
- Operate the blade or bur only after the appropriate anatomical landmarks and the intended surgical site have been confirmed.
- Disconnect power to the XPS Model 3000 before cleaning the unit.
- Blades, burs and irrigation tubing are disposable and intended for single-use only, UNLESS OTHERWISE MARKED.

THE FOLLOWING WARNINGS PERTAINING TO SUCTION LIPOPLASTY SHOULD ALSO BE CONSIDERED:

- This device will not, in and of itself, produce significant weight reduction.
- This device should be used with extreme caution in patients with chronic medical conditions, such as diabetes; heart, lung, or circulatory system disease; or obesity.
- The volume of blood loss and endogenous body fluid loss may adversely affect intra and/or postoperative hemodynamic stability and patient safety. The capability of providing adequate, timely replacement is essential for patient safety.

PRECAUTIONS

- To achieve electrical grounding reliability, connect the XPS Model 3000 console to hospital grade receptacles only.
- Only XPS High Speed Burs should be used above 6,000 rpm in forward with the StraightShot Magnum II Handpiece.
- XPS Microresector Blades should be operated in the oscillate mode only. Operating in the forward and reverse modes may cause damage to the blade. XPS Microresector burs should be operated in the forward mode only.
- The Visao/Xcalibur Hi-Speed Water-Cooled Drill is designed to work only with the XPS Model 3000. Use without water-bag will damage the motor in the handpiece.
- All reusable components of the device must be cleaned and sterilized and all disposable components replaced before using the device system on another patient.
- DO NOT allow saline/pump output to drip on console.
- Blade and Bur accessories are available for resection of soft tissue and bone for various surgical procedures. Use of this type of accessory is dependent on the intended application and patient needs. Sharp cutting powered accessories are capable of inducing bleeding and removal of significant tissue and bone.
- Use care in application of the moving cutting end to only appropriate anatomical landmarks and the intended surgical site when using rotating burs and blades. The use of powered reciprocating instruments may result in vibration related injury. Use appropriate precautions.
- Adequate visualization is to be employed when using rotating burs and blades. Discontinue powered application in the event of lack of visualization of the surgical site.

- Use methods at the operative site (airway, throat, head, neck or sinus cavity) to control bleeding that could compromise patient safety during at-risk surgery.
- DO NOT IMMERSE OR STERILIZE THE CONSOLE OR FOOTSWITCH.
- DO NOT immerse PowerSculpt, StraightShot Magnum, Powerforma, Xcalibur, Skeeter, StraightShot Magnum II handpieces, motors, or handpiece cables in any solution , except as detailed in the Cleaning section of this manual.
- Always inspect the components before and after use for any damage. If damage is observed, do not use the system until it is repaired.
- DO NOT use any parts other than Medtronic Xomed, Inc. components as damage or substandard operation could result.
- Temperatures higher than those stated may be used for handpiece sterilization when necessary to satisfy governmental or health care facility requirements so long as the temperature does not exceed 149°C. Heating above 149°C may damage components and will void the warranty.
- Regardless of which type of steam sterilization is used, it is extremely important that the handpiece is rapidly and completely dried before it is stored. If a vacuum drying cycle is not used following steam sterilization, moisture may be trapped within the handpiece causing corrosion and residue deposits, resulting in premature wear and a reduction in the functional life expectancy of the handpiece.
- DO NOT use organic solvents such as acetone or isopropyl alcohol to clean the handpiece, motor or cable.
- Attempted repair or evidence of attempted repair during the warranty period by anyone other than qualified Medtronic Xomed, Inc. service personnel will void the equipment warranty.
- This medical device complies with EN60601-1-2 safety standard for electromagnetic compatibility, requirements and test. However, if this equipment is operated in the presence of high levels of EMI or highly sensitive equipment, interference may be encountered and the user should take whatever steps are necessary to eliminate or reduce the interference.

THE FOLLOWING PRECAUTIONS PERTAINING TO SUCTION LIPOPLASTY SHOULD ALSO BE CONSIDERED:

- This device is designed to contour the body by removing localized deposits of excess fat through small incisions.
- Use of this device is limited to those physicians who, by means of formal professional training or sanctioned continuing medical education (including supervised operative experience), have attained proficiency in suction lipoplasty.
- Results of this procedure will vary depending upon patient age, surgical site, and experience of the physician.
- Results of this procedure may or may not be permanent.
- The amount of fat removed should be limited to that necessary to achieve a desired cosmetic effect

CUSTOMER SERVICE

U.S. CUSTOMER SERVICE

General customer service and technical support are available toll-free:
800-874-5797 or 904-296-9600
Monday-Friday
8:00 AM - 6:00 PM E.S.T.
www.MedtronicENT.com

INTERNATIONAL SERVICE

International customers should contact their local MEDTRONIC XOMED office:

AUSTRALIA:	61-2-9879-5999
CANADA:	905-826-6020
FRANCE :	33-4-7067-9800
U.K.:	44-44-1923-212213
GERMANY:	49-211-529-3209
NETHERLANDS	31-45-566-8000
BELGIUM	32-2-4560900

THE XPS MODEL 3000 HELP LINE

Should you need immediate help with a technical question or guidance through the appropriate protocol, just call the XPS Model 3000 Help Line at
1-800-874-5797.

NOTE

WHEN CONTACTING OUR CUSTOMER SERVICE AND TECHNICAL SUPPORT, PLEASE HAVE THE APPROPRIATE PRODUCT NUMBER, PRODUCT SERIAL NUMBER, DATE OF PURCHASE, AND NATURE OF INQUIRY AVAILABLE.

Product Number _____

Serial Number _____

Date of Purchase _____

WARRANTY AND REPAIR

LIMITED WARRANTY

A. This LIMITED WARRANTY provides assurance for the customer who purchases a Medtronic Xomed Product (hereinafter the "Product") that should the Product fail to function to Medtronic Xomed's published specifications during the term of this LIMITED WARRANTY (one year from the date of shipment for new Product, 90 days from date of shipment for refurbished or used Product), Medtronic Xomed will either replace, repair, or issue a credit (adjusted to reflect the age of the Product) for the Product or any portion thereof. This LIMITED WARRANTY is extended only to the buyer purchasing the Product directly from Medtronic Xomed or from its affiliate or its authorized distributor or representative.

B. To qualify for this LIMITED WARRANTY, the following conditions must be met:

(1) The Product must be used on or before its "Use By" or "Use Before" date, if applicable.

(2) The Product must be used in accordance with its labeling and may not be altered or subjected to misuse, abuse, accident or improper handling.

(3) Medtronic Xomed must be notified in writing within thirty (30) days following discovery of a defect.

(4) The Product must be returned to Medtronic Xomed within thirty (30) days of Medtronic Xomed receiving notice as provided for in (3) above.

(5) Upon examination of the Product by Medtronic Xomed, Medtronic Xomed shall have determined that: (i) the Product was not repaired or altered by anyone other than Medtronic Xomed or its authorized representative, (ii) the Product was not operated under conditions other than normal use, and (iii) the prescribed periodic maintenance and services have been performed on the Product.

C. This LIMITED WARRANTY is limited to its express terms. THIS LIMITED WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED WHETHER STATUTORY OR OTHERWISE, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. In no event shall Medtronic Xomed be liable for any consequential, incidental, prospective or other similar damage resulting from a defect, failure, or malfunction of the Product, whether a claim for such damage is based upon the warranty, contract, negligence or otherwise.

D. The exclusions and limitations set out above are not intended to, and should not be construed so as to, contravene mandatory provisions of applicable law. Users may benefit from statutory warranty rights under legislation governing the sale of consumer goods. If any part or term of this LIMITED WARRANTY is held by any court of competent jurisdiction to be illegal, unenforceable, or in conflict with applicable law, the validity of the remaining portion of the LIMITED WARRANTY shall not be affected, and all rights and obligations shall be construed and enforced as if this LIMITED WARRANTY did not contain the particular part or term held to be invalid.

CAUTION Attempted repair or evidence of attempted repair during the warranty period by anyone other than qualified Medtronic Xomed service personnel will void the equipment warranty.

A system that is not functioning properly should not be used until all necessary repairs have been made by Medtronic Xomed Service Personnel and the unit is tested to ensure that it is functioning in accordance with Medtronic Xomed specifications.

Domestic Repairs: When returning your system or components of your system for repair, please ensure that it is carefully packed to avoid any damage during shipping.

Please include the nature of the problem and all information needed to return the repaired system to your facility.

International Repairs: International customers should contact their local Medtronic Xomed office or local distributors (See "Customer Service" section).

CAUTION

Powered Handpiece Service Note:

Irrigation fluids, especially saline, and residual moisture can accelerate wear and corrosion causing premature failure of powered handpiece components. Care should be maintained to use a steam sterilizer with a dry cycle to remove excess moisture.

THE HANDPIECE SHOULD BE EVALUATED PRIOR TO EACH USE FOR SUITABLE OPERATING CONDITION. A HANDPIECE THAT OPERATES AT HIGH HEAT LEVELS, STALLS OR OPERATES INTERMITTENTLY, OR OPERATES IN A NOISY CONDITION IS A SIGN THAT SERVICE IS NECESSARY. THE HANDPIECE SHOULD BE RETURNED TO MEDTRONIC XOMED FOR SERVICE OR REPAIR. IT IS RECOMMENDED THAT A SECONDARY HANDPIECE BE AVAILABLE TO MINIMIZE ANY DOWNTIME AND INCONVENIENCE TO THE SURGICAL STAFF.

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CHAPTER 1
INTRODUCTION

This manual provides material for experienced technicians, but also includes fundamental information and various types of reference material, including:

- SERVICE AND REPAIR CONTACTS
- FUNCTIONAL OVERVIEW PROVIDES GENERAL NOMENCLATURE AND BASIC SETUP.
- TECHNICAL SPECIFICATIONS FOR THE CONSOLE AND ACCESSORIES.
- TROUBLESHOOTING GUIDE
- VERIFICATION TESTING

DEVICE DESCRIPTION

SYSTEM DESCRIPTION — The XPS 3000 System consists of a power control console, footswitches, connection cables, and assorted Handpieces to drive various burs, blades, drills, rasps, and cannulae.

XPS 3000 CONSOLE — Provides power to the selected handpiece. In addition to the StraightShot® M4 Microdebrider and Visao® High-Speed Otologic Drill, the system console also powers the StraightShot® Magnum® and Magnum® II handpiece, Powerforma® (High Speed Drill), Xcalibur® Hi-Torque and Hi-Speed Drills, and Skeeter® (microdrill) handpieces. It includes an integrated irrigation pump for irrigation of blades and burs and a second pump for motor coolant of the Visao® High-Speed and Xcalibur® Hi-Speed Otologic Drills.
FOOTSWITCH — The Single Function footswitch controls handpiece speed, the Multifunction footswitch controls handpiece speed, rotation mode, and footswitch mode.

X**P**S® STR**AIGHTSHOT® M4 Microdebrider** — Features a finger wheel that allows the user to rotate the cutting tip of specially designed straight and curved rotatable blades. It is also compatible with non-rotating blades and burs. It includes a locking mechanism to prevent inadvertent rotation of non-rotating blades. The lightweight design combines high power and precision performance and can operate in forward mode of 12,000 rpm for bur operation and 5,000 rpm in oscillate for blade operation. The StraightShot® M4 also provides irrigation tubing management grooves to keep tubing out of the surgeon's way during a procedure.

STRAIGHTSHOT MAGNUM II MICRORESECTOR HANDPIECE — Features a convenient locking mechanism and allows adjustability of blade or bur tip alignment. The lightweight design combines high power and precision performance and can operate in forward mode at 12,000 RPM for bur operation and in oscillate mode at 5,000 RPM for blade operation.

STRAIGHTSHOT MAGNUM HANDPIECE — Features a convenient locking mechanism and allows adjustability of blade or bur tip alignment. The lightweight design combines high power and precision performance.

Visao® **High**-S**peed Otologi**c D**rill** — The lightweight design is used in otologic bone drilling operations. It may be used with either standard burs or with Visao® High-Speed Curved Burs.

XCALIBUR HI-TORQUE AND HI-SPEED (WATER-COOLED) OTOLOGIC DRILLS — Includes two motor assemblies, one hi-torque and one hi-speed (water-cooled); and one straight and one angled handpiece attachment. It is used in otologic bone drilling operations.

SKEETER ULTRA-LITE OTO-TOOL — A slender, lightweight drill handpiece and burs specifically designed for use in middle ear surgical procedures, including stapes footplate procedures. The Skeeter may be powered from the XPS 3000 console, XPS 2000 console, or from a battery powered, variable speed, foot control.

POWERSCULPT HANDPIECE — Features a convenient locking mechanism and allows adjustability of various handpiece attachments. The lightweight handpiece was designed specifically for suction lipoplasty.

POWERSCULPT BILATERAL FOOTSWITCH — Designed for use only with the PowerSculpt handpiece. It is a continuous ON or OFF switch.

POWERFORMA OTOLOGIC DRILL — Straight and angled drill Handpieces for otologic bone drilling. The Powerforma connects, via an adapter plug, to the XPS 3000 and XPS 2000 consoles. .

CHAPTER 2
SERVICE/REPAIR PROCEDURE

U.S. CUSTOMERS

Should your console or related equipment malfunction, MEDTRONIC XOMED provides, at no charge, loaner equipment shipped to your facility by UPS or Federal Express for use while your equipment is being repaired by MEDTRONIC XOMED. Please adhere to the following guidelines:

1. When a loaner console is ordered, please reuse the shipping material and carton when you return your console to MEDTRONIC XOMED. Insure the unit.
2. When a loaner is not ordered, please package the console as safely as possible and insure.
3. A Service Request number is required on repairs. A copy of your purchase order is required. Make certain the purchase order includes the following:

    - Shipping and billing information
    - Purchase order number
    - Contact person
    - Phone number
    - Description of malfunction
    - Your MEDTRONIC XOMED account number

4. Please indicate preferred method of return shipment. Otherwise the unit will be shipped back via UPS 2 day air.
5. The customer will be responsible for freight charges on non-warranted units.
6. When you have loaner equipment and you receive your repaired unit, please package the loaner equipment as safely as possible using the foam provided with your repaired equipment. Include paperwork indicating the unit is a loaner.
7. Loaner equipment not received by MEDTRONIC XOMED within 30 days from the date that repaired equipment is shipped will be invoiced at full purchase price.

ATTENTION:

THE XPS MODEL 3000 IS NOT USER SERVICEABLE. Attempted repair or evidence of attempted repair by the customer or anyone other than Medtronic Xomed personnel will void the equipment warranty.

INTERNATIONAL CUSTOMERS

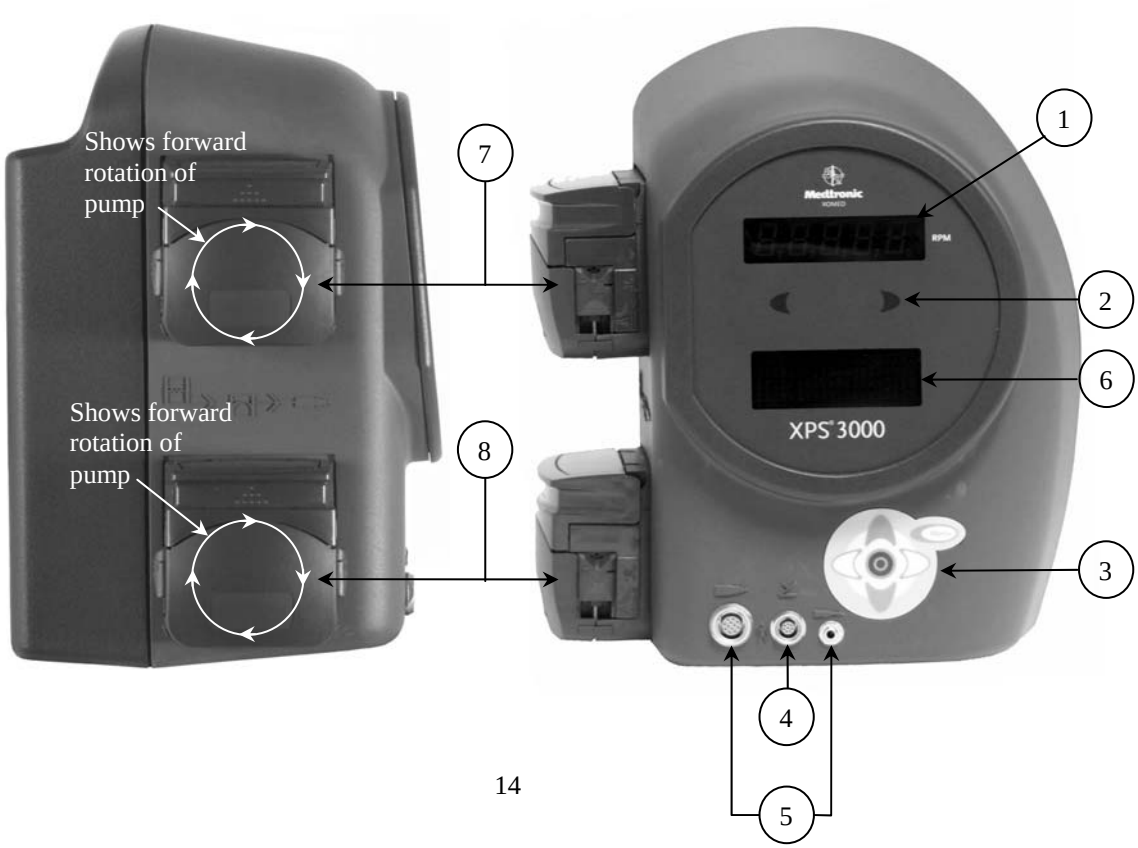
International Customers should contact their local Medtronic Xomed office or distributor.

CHAPTER 3
FUNCTIONAL OVERVIEW

XPS 3000 CONSOLE DESCRIPTION

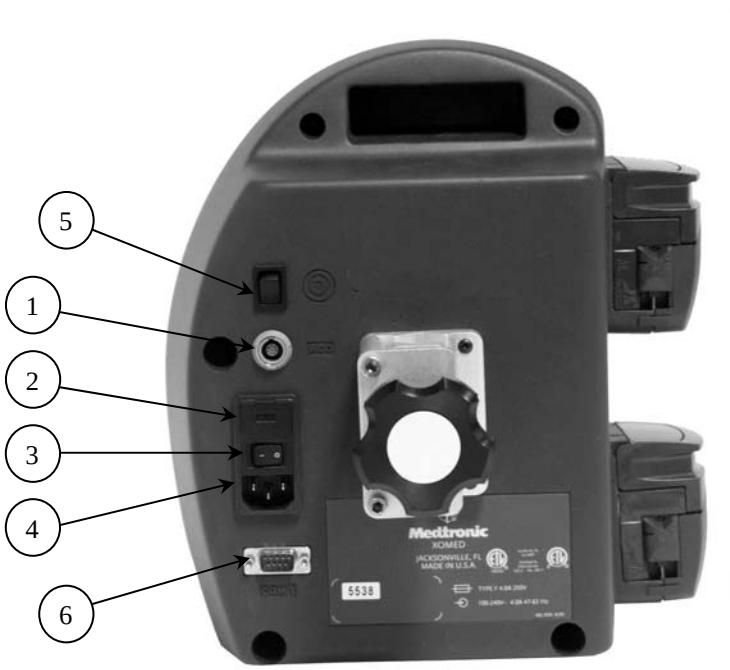
FRONT CONSOLE

1. **SPEED DISPLAY** – When the system is running, the actual operating speed of the handpiece displays. When inactive, the display shows the top speed set by the operator.
2. **ROTATION INDICATOR** – Displays rotation mode (oscillate, forward or reverse (depending on handpiece)). Lights indicate selected rotation. Rotation may be selected using either the multi-function footswitch or with the center control button in the normal mode.
3. **CONTROL BUTTON CLUSTER** – Operates in two modes, Normal and Procedure. In Normal operation, center button controls direction (oscillate, forward or reverse (depending on handpiece)), top and bottom buttons control speed (increase and decrease), and left and right button control rate of irrigation (decrease and increase). Depressing the menu button activates the Procedure Mode. Arrow buttons control the cursor and the center button is the Select button. Operation of the speed and procedure functions is described below.
4. **FOOTSWITCH CONNECTOR** – Connect the footswitch to the console here. During standard operation the footswitch must be connected to operate the active handpiece.
5. **HANDPIECE CONNECTORS** – Connect the appropriate handpiece to the console here. (Large connector for all Handpieces except for Skeeter handpiece.)
6. **PROCEDURE AND CURRENT OPERATIONS DISPLAY** – In operating mode, displays procedure-blade or bur setting and irrigation pump rate. In procedure selection/menu mode, it displays a choice of procedures, allowing the user to choose suggested operational settings for the current procedure.
7. **VISAO/XCALIBUR HI-SPEED WATER COOLANT PUMP** – Pumps cooling fluid for the Water -Cooled drill motor assembly.
8. **HANDPIECE IRRIGATION PUMP** – Pumps fluid through a tubing set to the blade or bur.



REAR CONSOLE

1. **ENDOSCRUB CABLE CONNECTOR** – Accepts accessory cable which powers the Endoscrub 2.
2. **FUSE ACCESS** – REPLACE ONLY WITH 250v, 4.0A, Type F, 5 x 20mm fuses.
3. **POWER SWITCH** – Press the power switch to the "l" position to turn on the system. Press the switch to the "O" position to turn the system off.
4. **POWER CORD CONNECTOR** – Hospital grade power cord connects here.
5. **MANUAL START STOP BUTTON** – In the case of footswitch failure the intraoperative button allows circulation nurse to manually turn handpiece operation on and off.
6. **DB-9 CONNECTOR –** Connector for future data exchange.



XPS 3000 SET-UP

CAUTION

Inspect components for damage before use. Do not operate if components are damaged.

CABLE CONNECTIONS

To connect the cables to the console:

1. Insert the cable connectors by aligning the red dot on the cable connector with the red dot on the console connector.
2. Push connectors together. They should lock in place.

To disconnect the cables from the console:

1. Grasp the cable connector and gently pull back on the collar of the connector.
2. The connector will disconnect.

CAUTION

Grasp the cable connector; do not pull on the cable.

LANGUAGE SELECTION

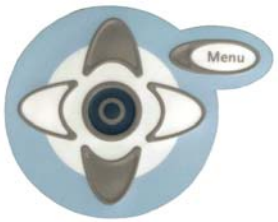
The front panel displays text in English, Danish, Dutch, Finnish, French, German, Italian, Portuguese, Spanish and Swedish. To change the language selection, simultaneously press the left and right arrow key on the control button cluster. Next, menu will appear on the display showing the language choices. Use the arrow keys to move the cursor to the desired language and press the center key to select.

CONSOLE SET-UP

PRECAUTIONS

- System components should be operated and inspected for damage prior to use. **DO NOT USE SYSTEM IF DAMAGE IS APPARENT.**
- Do not allow the console to get wet. If liquid enters the console, damage could occur.

1. Plug the power cord into the console and into the wall outlet.
2. Connect the handpiece(s) to the appropriate console connector(s).
3. Connect the footswitch cable to the console. See next section for instructions on footswitch operation.
4. Turn the console on by pressing the power switch on the back panel. The console will display Handpiece default speed rotation procedure setting.
5. The following tables (step 7) show the default settings in Normal and Procedure Mode.
6. The control button cluster can control speed, direction, irrigation rate, and, in Procedure Mode (depress menu button), give the operator suggested operating speeds for different procedures of the control button.



7. Default speeds may be adjusted by pressing top and bottom buttons to increase and decrease speed. Default pump flow rate may be adjusted by pressing right (increase) and left (decrease) buttons. Direction (forward, reverse, oscillate) can be changed by pressing the center button.

Default speeds are listed below. (* Not Applicable)

HANDPIECE	OSCILLATE	FORWARD	REVERSE	DEFAULT MODE
Visao High Speed Otologic	N/A	60,000 RPM	60,000 RPM	
Straightshot M4	5,000 RPM	6,000 RPM	N/A	OSCILLATE
StraightShot Magnum II	5,000 RPM	6,000 RPM	N/A	OSCILLATE
StraightShot Magnum	3,000 RPM	6,000 RPM	N/A	OSCILLATE
Powerforma	*	43,000 RPM	43,000 RPM	FWD
PowerSculpt	*	3,000 RPM	N/A	FWD
Xcalibur Hi-Torque Motor	*	43,000 RPM	43,000 RPM	FWD
Skeeter	*	12,000 RPM	N/A	FWD
Xcalibur Hi-Speed Motor	*	60,000 RPM	60,000 RPM	FWD

Handpiece operating ranges are listed below.

HANDPIECE	ROTATION MODE	LOW LIMIT	HIGH LIMIT
Visao High Speed Otologic	FWD or REV	10,000 RPM	80,000 RPM
Straightshot M4	FWD	500 RPM	12,000 RPM
Straightshot M4	OSCILLATE	500 RPM	5,000 RPM
StraightShot Magnum II	FWD	500 RPM	12,000 RPM
StraightShot Magnum II	OSCILLATE	500 RPM	5,000 RPM
StraightShot Magnum	FWD	300 RPM	6,000 RPM
StraightShot Magnum	OSCILLATE	300 RPM	3,000 RPM
Powerforma	FWD or REV	10,000 RPM	52,000 RPM
PowerSculpt	FWD	300 RPM	6,000 RPM
Skeeter	FWD	6,000 RPM	12,000 RPM
Xcalibur Hi-Torque	FWD or REV	10,000 RPM	52,000 RPM
Xcalibur Hi-Speed	FWD or REV	10,000 RPM	80,000 RPM

NOTE: A recommended set speed of 3000-4500 RPM's should be used when performing lipoplasty with the PowerSculpt handpiece.

8. Rotation Mode — Changed by either pressing the Rotation Control button (in the center of the control button cluster) on the console or, if the multifunction footswitch is used, depressing and releasing the left pedal.

MULTIFUNCTION FOOTSWITCH

The multifunction footswitch allows selection of handpiece speed, rotation mode, and footswitch mode. The footswitch cable connects with the console by a push connector.

1. **Right Pedal** — The right pedal provides control of handpiece speed. When in the VARIABLE operating mode, handpiece speed increases as the pedal is depressed. In the NORMAL operating mode, the handpiece automatically operates at the MAX SET SPEED displayed on the console when the pedal is depressed. The right pedal also activates the irrigation pump if connected.
2. **Left Pedal** — Depressing and releasing the left pedal changes the ROTATION direction (oscillate, forward, or reverse) of the handpiece.
   NOTE: Rotation mode may only be changed when the handpiece is <u>not</u> running.
3. **Top Button** — Depressing and releasing this button changes the FOOTSWITCH MODE (Variable or ON/OFF).

CAUTION

- **DO NOT** immerse the footswitch.
- **DO NOT** sterilize the footswitch.

SINGLE FUNCTION FOOTSWITCH

The single function footswitch operates only in a variable mode. It controls handpiece speed, which increases as the pedal is depressed. The pedal also activates the irrigation pump if connected. The footswitch cable connects with the console by a push connector.

XPS® Multifunction Footswitch, SINGLEPEDAL, 1895420

The multifunction footswitch allows control of handpiece speed, rotation mode, and footswitch mode. The footswitch cable connects with the console by a push connector.

1. Pedal — The pedal provides control of handpiece speed. When in the VARIABLE operating mode, handpiece speed increases as the pedal is depressed. In the START/STOP operating mode, the handpiece automatically operates at the MAX SET SPEED displayed on the console when the pedal is depressed. The pedal also activates the irrigation pump if connected.
2. Left Button — Depressing and releasing this button changes the ROTATION direction (oscillate, forward, or reverse) of the handpiece. Note: Rotation mode may only be changed when the handpiece is not running.
3. Right Button — Depressing and releasing this button changes the FOOTSWITCH MODE (Variable or Start/Stop).

CHAPTER 4
TECHNICAL SPECIFICATIONS

HANDPIECES - XPS® StraightShot® M4 Microdebrider / StraightShot® Magnum® II / LandmarX® Magnum® II / XPS® StraightShot® III

Part No. 1898200T XPS® StraightShot® M4 Microdebrider
1897200 StraightShot® Magnum® II Handpiece
1897200T LandmarX® Magnum® II Handpiece
1897201 XPS® StraightShot® III Handpiece (Japan only)
Speed 500-5,000 rpm oscillate
500-12,000 rpm forward
Size 14.3 cm length x 1.8 cm width (1898200T)
17 cm length x 1.6 cm diameter (1897200, 1897200T, and 1897201)
Weight 228 g 1898200T
240 g 1897200
254 g 1897200T
240 g 1897201
Duty Cycle The XPS® StraightShot® M4, StraightShot® Magnum® II, LandmarX® Magnum® II, and XPS® StraightShot® III Handpieces under full load are rated for intermittent operation per the following:
Maximum On Time 60 seconds
Minimum Off Time 30 seconds

VISAO™ AND XCALIBUR® DRILLS

Part No. 3334800 Visao™ High-Speed Otologic Drill
3334800T Visao™ High-Speed Otologic Drill, IGS Trackable
3333700 Xcalibur® Straight Hi-Torque Handpiece Attachment
3333705 Xcalibur® Straight Hi-Speed Handpiece Attachment
3333750 Xcalibur® Angled Hi-Torque Handpiece Attachment
3333755 Xcalibur® Angled Hi-Speed Handpiece Attachment
3333840 Xcalibur® Hi-Speed Motor Assembly, Water-Cooled
3333850 Xcalibur® Motor Assembly (Hi-Torque)
Speed 10,000-80,000 rpm forward/reverse, Visao™ High-Speed Otologic Drill, Water-Cooled (3334800 and 3334800T)
10,000-52,000 rpm forward/reverse Xcalibur® Hi-Torque Motor (3333850)
10,000-80,000 rpm forward/reverse, Xcalibur® Hi-Speed Motor, Water-Cooled (3333840)
Size 16.0 cm length x 2.0 cm diameter 3334800
16.0 cm length x 2.0 cm diameter 3334800T
10.5 cm length x 2.0 cm diameter 3333700
9.8 cm length x 2.0 cm diameter 3333705
11.7 cm length x 2.0 cm diameter 3333750
11.2 cm length x 2.0 cm diameter 3333755
12.0 cm length x 2.0 cm diameter 3333840
12.0 cm length x 2.8 cm diameter 3333850
Weight 148 g 3334800
148 g 3334800T
58 g 3333700
59 g 3333705
78 g 3333750
80 g 3333755
175 g 3333840
195 g 3333850
Duty Cycle The Visao™ High-Speed Otologic Drill and Xcalibur® Drill under full load are rated for intermittent operation per the following:
Maximum On Time 60 seconds
Minimum Off Time 30 seconds

POWERFORMA DRILL

Ref. No. 3327700 Straight Handpiece
3327750 Angled Handpiece

Speed 10,000-52,000 RPM forward/reverse

Size 19.1 cm, Diameter 2.9 cm Straight Length
19.7 cm, Diameter 2.9 cm Angled Length

Weight Straight Handpiece 165 g
Angled Handpiece 182 g

Duty Cycle Powerforma Handpieces under full load are rated for intermittent operation per the following:
Maximum on Time 60 seconds
Minimum off Time 30 seconds

SKEETER ULTRA-LITE OTO-TOOL

Ref. No. 3155601 Straight Handpiece Attachment

Speed 12,000 RPM forward

Size 17 cm length x 1.6 cm diameter

Weight 57 g Straight Attachment

Duty Cycle Continuous run

CONSOLE

Ref. No. 1897101
1897102

Electrical Input Power 100-240 VAC, 47-63 Hz, 4 A

Size 20 cm Width x 28 cm Height x 18.5 cm Depth

Weight 4.5 kg

Class Class I Medical Device per EN 60601-1

MULTIFUNCTION FOOTSWITCH

Ref. No. 1895400

Size 18 cm Length x 18.5 cm Width x 6.3 cm Height

Weight 1.8 kg

Protection Against Water Ingress IPX8

XPS® multifunction footswitch, single pedal

Part No. 1895420

Size 18 cm Length x 18 cm Width x 3.8 cm Height

Weight 1.8 kg

Protection Against Water Ingress IPX8

SINGLE FUNCTION FOOTSWITCH

Ref. No. 1895410

Size 11.5 cm Length x 8.9 cm Width x 5.6 cm Height

Weight 0.8 kg

Protection Against Water Ingress IPX8

COMPLIANCE

EN60601-1
EN60601-1-2
UL60601-1
CSA22.2 No. 601.1
ETL Listed Medical Device

RECOMMENDED ENVIRONMENTAL CONDITIONS

Operating
Temperature: .....10° to 35°C
Humidity: .....10% to 90% RH
Barometric Pressure: .....700 to 1060 hPa

Storage
Temperature: .....-40° to 60°C
Humidity: .....0% to 100% RH
Barometric Pressure: .....500 to 1060 hPa

XPS 3000 SYSTEM

This device meets CISPR 22 Level B emission standard per EN 60601-1-2.
This device complies with UL60601-1, CSA 22.2 No. 601.1, and EN60601-1.

CHAPTER 5
TROUBLESHOOTING GUIDE

XPS 3000 Troubleshooting Guide		
Symptom	**Issue**	**Action**
Console default parameters incorrect (i.e. unable to select maximum speed of handpiece)	Moisture ingress in cable conflicts with handpiece recognition	Run a dry cycle when sterilizing, if problem persists, have handpiece serviced by MDT Xomed
Cooling pump does not run with Water-Cooled Xcalibur	Moisture ingress in cable conflicts with handpiece recognition	Run a dry cycle when sterilizing, if problem persists, have handpiece serviced by MDT Xomed
Handpiece runs slow or "bogs" down	Moisture ingress in cable conflicts with handpiece recognition	Run a dry cycle when sterilizing, if problem persists, have handpiece serviced by MDT Xomed
Handpiece Connected but Console reads "No Handpiece" when footswitch pressed	Moisture ingress in cable conflicts with handpiece recognition	Run a dry cycle when sterilizing, if problem persists, have handpiece serviced by MDT Xomed
Handpiece fails to rotate and speed display reads "0"	• Failed Handpiece Motor or • Failed Motor Driver	• Have handpiece serviced by MDT Xomed or • Have Motor Controller Board serviced by Medtronic Xomed
Handpiece fails to rotate	Failed footswitch	Disconnect footswitch, use Manual Start/Stop rocker switch on rear of console
Little or No Irrigation Flow	Tubing Set improperly seated in pump	Reposition tubing in pump, verify pump lid is fully closed with the fluid flow from left to right
Pump does not rotate	• Failed pump motor/cable assembly or Failed microprocessor board	• Have pump motor/cable assembly serviced by Medtronic Xomed or • Have Microprocessor board serviced by Medtronic Xomed
Keypad not responding	• Failed keypad or • Failed master processor	• Have keypad serviced by Medtronic Xomed or • Have master processor/microprocessor serviced by Medtronic Xomed
Display reads, "COdE2"	Motor Fault	Cycle power
Display reads, "COdE3"	SVDC Power Supply Failure	• Cycle power • If problem persists, have Power Supply serviced by Medtronic Xomed
Display reads, "COdE4"	12VDC Power Supply Failure	• Cycle power • If problem persists, have Power Supply serviced by Medtronic Xomed
Display reads, "COdE6"	48VDC Power Supply Failure	• Cycle power • If problem persists, have Power Supply serviced by Medtronic Xomed
Display reads, "hPEr"	Master processor or slave processor fail	Have Microprocessor Board serviced by Medtronic Xomed
Display reads, "SpdEr"	Master processor or slave processor fail	Have Microprocessor Board serviced by Medtronic Xomed
Display reads, "dirEr"	Master processor or slave processor fail	Have Microprocessor Board serviced by Medtronic Xomed
Display reads, "vErEr"	Master processor or slave processor fail	Have Microprocessor Board serviced by Medtronic Xomed
Display reads, "ChKEr"	Master processor or slave processor fail	Have Microprocessor Board serviced by Medtronic Xomed

Symptom	Issue	Action
Console lights fail to illuminate	Power Inlet Fuses blown	Replace fuses with 4.00 A, 250V, Type F fuses (P/N 11270037)
Blade or Bur Malfunction		
	Appears to be damaged or defective	Remove and replace defective blade or bur.
	Blade or bur is not firmly seated	Pull back locking collar and reseat the blade or bur.
	Blade opening is obstructed	Remove blade from surgical site and submerse the blade tip in sterile water with suction connected to the handpiece to evacuate the obstruction, or use stylette to clear blade. The suction tube may be removed from the handpiece and inserted over the end of the blade and blade activated to evacuate the obstruction from the tip of the blade.
	Blade or bur is leaking irrigant	• Check for proper blade or bur insertion by pulling back locking collar, and reseating blade or bur. • Check blade for obstruction. If visible, evacuate obstruction by one of the above methods. • Inspect suction connection on handpiece and at suction canister, and if suction tubing is disconnected, connect it. • Remove and inspect suction tubing, and if obstructed, remove obstruction.
	Burs wobble in Xcalibur or Powerforma Handpieces	• Reduce handpiece operating speeds. • Use burs that are rated for the console speed selected. • If necessary, use extended bir guards with Xcalibur drills for 64 mm and 75 mm burs. • Operate hand piece at 50% of full speed for 64 mm and 75 mm burs. • Select a new bur.
	Console lights illuminate but handpiece fails to rotate.	• Inspect handpiece cable connections, and ensure that handpiece cable connector is firmly seated.
	Blade or bur continues to malfunction.	• Remove and replace blade or bur. • Call Customer Service.

If any equipment continues to malfunction contact:

CUSTOMER SERVICE
800-874-5797 or 904-296-9600
Monday-Friday
8:00 AM - 6:00 PM E.S.T.
www.MedtronicENT.com

CHAPTER 6
VERIFICATION TEST

MATERIALS AND EQUIPMENT:

Assembly Equipment:
Any of the following Digital Multi-meters: Fluke 75, 87, 27 or equivalent.
Powerforma, Skeeter, and Straight Shot Handpieces
Hi speed Xcalibur water cooled Handpiece
XPS Dual Footswitch
Solder Iron/Desolder Iron
ESD workstation
Bio-Tek 601 Pro Safety Analyzer
QuadTech, Sentry 20 AC/DC Hipot Tester
Power Cord
Xcalibur Coolant Tubing Set
Endoscrub 2 with cable

CAUTION:
HIGH SPEED HANDPIECE AND SHARP TOOLS (BURS).
HIGH PROBABILITY OF SERIOUS INJURY AND/OR EQUIPMENT DAMAGE IF CONTACT IS MADE WITH HANDPIECE TOOLING.

FUNCTIONAL TESTING

Equipment:

XPS Dual Footswitch	Magnum II Handpiece	Skeeter Handpiece
Xcalibur Handpiece	Power Cord	

For XPS Consoles not made for domestic distribution, a California power supply or equivalent, must also be used.

POWER UP TEST

1. Attach power cable to console and apply power. Do not attach any accessories yet.
   - Verify that all segments in the numeric display illuminate for 2 or 3 seconds, followed by all zero's for 1 or 2 seconds.
   - During power up the character display will briefly display the software revision.
2. Once unit detects that there are no handpieces attached to it, the numeric display will read "no HP", and character display will read "INSERT HANDPIECE".
   - Verify that Rotation Indicators are off.
3. Remove power from unit.

TESTING CONSOLE with MAGNUM II HANDPIECE

1. Insert Magnum II Handpiece into console.
2. Apply power.
   - Verify that numeric display reads "3000".
3. Character display should default to:

Line 1:	SINUS
Line 2:	BLADE
Line 3:	OSCILLATE
Line 4:	IRRIGATION 60%

ROCKER SWITCH

1. Press Rocker Switch.
   - Verify pump and handpiece operate.
2. Release Rocker Switch.
   - Verify the handpiece stopped and irrigation pump ran in reverse briefly before stopping.
3. Place unit in "OSCILLATE" mode.
   - Verify Handpiece alternates between forward and reverse.
   - Verify Pump operates.
4. Release Rocker Switch.
   - Verify the handpiece stopped and irrigation pump ran in reverse briefly before stopping.

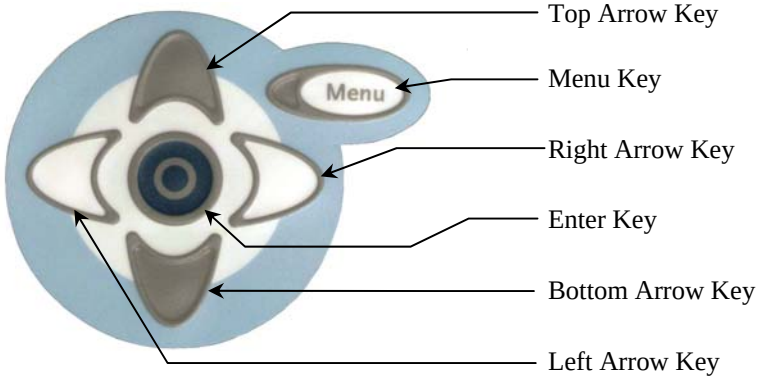
TOUCHPAD KEY FUNCTIONS

NOTE: An audible beep should be heard whenever one of the Touchpad Keys is pressed.

1. Insert Magnum II Handpiece into console.
2. Press the "Menu" key.
   - The character display shows:

Line 1:	<<PROCEDURES>>
Line 2:	▸ SINUS PLASTIC
Line 3:	LARYNGEAL ADENOID
Line 4:	EXIT

3. Test cursor navigation.
   a. Use the Up, Down, Left and Right arrow keys to check cursor navigation. The cursor should move in accordance to the key that is pressed.
4. Select one of the choices available other than EXIT, and press the ENTER key.
   - Verify the selected procedure is displayed.
5. Find the EXIT option and press ENTER.
   - The character display will return to the main menu while displaying the selected procedure's name in the first line.



6. Return to the "SINUS" menu by pressing the MENU key, and the ENTER key twice.
7. Test PRIME function.
   a. Press and hold RIGHT ARROW key until the word PRIME is displayed next to IRRIGATION, continue to hold key down for a few seconds.
      - Verify Irrigation Pump starts and rotation is forward.
8. Test DRIP function.
   a. Press LEFT ARROW key until the word DRIP is displayed next to IRRIGATION.
      - Irrigation pump should start running.

NOTE: In the following tests, make sure irrigation pump runs whenever handpiece is in operation, either in FORWARD or OSCILLATE mode.

9. Test FORWARD mode.
   a. With Magnum II Handpiece connected, press the ENTER key.
      - Console should change from OSCILLATE to FORWARD mode.
   b. Press the rocker switch to test.
      - When looking from BEHIND the handpiece, it should rotate clockwise.
   c. Test FORWARD mode at different speeds:
      - Increment speed by pressing the UP ARROW key and decrement it by pressing the DOWN ARROW key. Speed should increase or decrease by 100 RPM each time a key is pressed. For faster speed adjustment, press and hold either key. Speed adjustments should be tested and should work with rocker switch released (motor stopped) and with rocker switch depressed (motor running). Maximum forward speed is 12000 RPMs and minimum speed is 500 RPMs.
      - In FORWARD mode, only the right rotation Indicator should be illuminated.

10. Set console to OSCILLATE mode.
    a. Test OSCILLATE mode at different speeds by following the same procedure as in step 9.
    b. In OSCILLATE mode maximum speed is 5000, and minimum speed is 500.
    c. In OSCILLATE mode, both rotation Indicators should be illuminated.
11. Irrigation Pump Test (with handpiece running).
    a. Press the RIGHT ARROW KEY repeatedly.
        • Verify the irrigation rate increases and display increases in 5% increments.
    b. Press the LEFT ARROW KEY repeatedly.
        • Verify the irrigation rate decreases and display decreases in 5% increments.
    c. With handpiece stopped repeat steps a, and b.
        • Verify the irrigation rate increases/decreases and display changes in 5% increments.

DUAL FOOTSWITCH

1. Connect Dual Footswitch.
2. Press Rocker Switch.
    • Verify that it does not work with footswitch connected.
3. Test NORMAL/VARIABLE pushbutton on footswitch.
    a. Press footswitch pushbutton once.
        • Verify the message “START/STOP FOOTSWITCH” appears briefly on character display.
    b. Press pushbutton again.
        • Verify the message “VARIABLE FOOTSWITCH” appears briefly on character display. Footswitch will continue to operate in variable speed mode.
4. Press and release left pedal.
    • Verify character display changes between OSCILLATE and FORWARD mode.
5. Set console in OSCILLATE mode.
6. Gradually depress right pedal on footswitch.
    • Verify that RPM speed increases smoothly up to set speed in handpiece.
    • The gradual acceleration should also be reflected in the console’s numeric display.
7. Gradually elevate right pedal on footswitch.
    • Verify that RPMs decrease smoothly in the handpiece.
    • The gradual deceleration should also be reflected in the console’s numeric display.
8. Release footswitch.
    • Verify that the handpiece and irrigation pump stop.
9. Press NORMAL/VARIABLE pushbutton on footswitch to change from variable speed to START/STOP operation.
10. Press right pedal on footswitch.
    • Verify that the handpiece and irrigation pump start at full speed.
11. Release right pedal on footswitch.
    • Verify handpiece and irrigation pump stop (irrigation pump should reverse momentarily).
12. Using foot pedal/button set console in FORWARD mode.
13. Repeat steps 6 through 11 in FORWARD mode.

TESTING CONSOLE with XCALIBUR HIGH SPEED HANDPIECE

1. Replace Magnum II Handpiece with **Xcalibur** Hi-Speed Handpiece.
    • Connect the Xcalibur coolant tubing set.
    • Numeric display should indicate 60000 PRM.
    • Right Rotation Indicator should illuminate.
    • Character display should indicate the following:

Line 1:	MASTOID
Line 2:	BUR
Line 3:	FORWARD
Line 4:	IRRIGATION 90%

2. Press MENU key.
    • The message “NO MENU OPTIONS AVAILABLE” should be displayed.
3. Test prime function.
    a. Press and hold RIGHT ARROW key until the word PRIME is displayed next to IRRIGATION and hold for a few seconds.
        • Verify both pumps start running.

4. Test DRIP function.
   a. Press LEFT ARROW key until the word DRIP is displayed next to IRRIGATION.
      - Verify irrigation pump starts.
5. Depress speed control (right pedal) on footswitch gradually.
   - Verify handpiece spins clockwise when viewed from BEHIND and speed changes smoothly.
   - Numeric display should reflect speed variations accordingly.
   - Verify that when pedal is fully depressed handpiece speed is between 55000 to 60000 RPM.
   - Verify that Cooling and Irrigation pumps start and stop together with handpiece.
   - Irrigation pump should run in reverse briefly when handpiece stops.
   - Verify pump rotation. Both pumps should rotate forward.
6. Set console in REVERSE mode, using either the ENTER key in Touchpad or the Left pedal in footswitch.
   - Verify left Rotation Indicator should illuminate.
7. Depress speed control (right pedal) on footswitch gradually.
   - Verify that handpiece spins counterclockwise when viewed from the rear, and that speed changes smoothly.
   - Numeric display should reflect speed variations accordingly.
   - Verify Handpiece speed equals 60,000 RPMs +/- 5% (57000 – 63000 RPM), when it reaches its limit.

XCALIBUR HIGH SPEED TEST (60,000 + RPMs)

1. Set console in FORWARD mode.
2. Increase speed with RIGHT ARROW key until the following message appears.

Line 1:	WARNING!
Line 2:	REQUIRES THE USE
Line 3:	A HIGH SPEED BUR
Line 4:	‣ EXIT CONTINUE

3. To return to 60,000 RPM mode, press the ENTER key.
   - Numeric display will show 60000 in either FORWARD or REVERSE modes.
4. To raise RPM speed above 60,000, move cursor with the RIGHT ARROW key to “CONTINUE” and press the ENTER key.

NOTE: When RPM speed set point is decreased to any speed under 60000 RPM in either FORWARD or REVERSE mode, there will be no Warning messages. However, whenever speed set point is increased in either mode, the High Speed Bur Warning message will be displayed.

NOTE: If handpiece is removed when the High Speed Bur Warning message is on the character screen, a “H P Err” message will flash in the numerical display, together with the right or left rotation indicator. When Handpiece is reattached, this message will clear.

5. Test 80,000 RPM operation.
   a. Fully depress speed control pedal on footswitch and verify that maximum speed of 80,000 RPMs is reached.
   b. Release speed control pedal.
      - Verify handpiece stops.
6. Press NORMAL/VARIABLE pushbutton on footswitch to change from variable speed to START/STOP operation.
7. Press right pedal on footswitch.
   - Verify handpiece starts at full speed together with irrigation and cooling pumps.
8. Release right pedal on footswitch.
   - Verify handpiece stops.
9. Repeat steps 1 through 8 in reverse mode.

TESTING CONSOLE with SKEETER HANDPIECE

1. Connect Skeeter Handpiece to console.
   - Display indicates 12,000 RPMs, and right rotation indicator will be illuminated.
   - Character Display should indicate the following:

Line 1:	MIDDLE EAR
Line 2:	SKEETER
Line 3:	FORWARD
Line 4:	IRRIGATION OFF

2. Press the MENU key.
   - The following message will be displayed “NO MENU OPTIONS AVAILABLE”.
3. Depress direction (RIGHT or LEFT ARROW) keys.
   - It should have no effect on ROTATION INDICATORS or functions of console.
4. Depress left pedal on footswitch.
   - It should have no effect on Skeeter or on rotation indicators or functions of console.
5. Depress right pedal on footswitch and watch numeric display.
   - RPM speed on Skeeter should increase or decrease smoothly as pedal is gradually depressed or released.
   - Numeric display should reflect this change.
   - Verify handpiece spins clockwise when viewed from the rear.
6. Release footswitch.
   - Verify handpiece stops.
7. Disconnect footswitch.
   - Verify right ROTATION INDICATORS is lit.
   - Verify that Skeeter operates when Rocker switch is depressed.
8. Disconnect Skeeter.
   - Verify the numeric display indicates “no HP” and Character Display indicates “INSERT HANDPIECE”.

TEST ENDOSCRUB PUMP

1. Attach Endoscrub Pump to ACCESSORIES (ACC connector in back of XPS-3000 console).
2. Set pump to Prime.
   - Verify that pump runs.

BIO-TEK SAFETY TEST

NOTE: Verify testing area is clear and unit to be tested is insulated from other metal surfaces and is not in contact with anything else.

1. Insert power plug of BioTek 601 Safety Analyzer into wall outlet.
2. Insert the power cord from the console to be tested (UUT) into the front of the analyzer.
3. Attach the probe to the front Handpiece receptacle nut on the UUT.
4. Turn the UUT power on.
5. Perform the safety test for a type B applied part per UL60601-1
6. When performing the Earth Resistance Test, first check the resistance with the red grabber lead attached to the front Handpiece.
7. When the test is complete and the beeping has stopped, move the red grabber lead to one of the screws on the pole clamp and re-run the earth resistance test.

DIELECTRIC WITHSTAND TEST

NOTE: Verify testing area is clear and unit to be tested is insulated from other metal surfaces and is not in contact with anything else.

1. Plug power cord to the Quad-Tech Hi-pot tester into the wall outlet.
2. Plug the power cord from UUT into the test adapter.
3. Plug the test adapter into the Quad-Tech Hi-pot tester.
4. Test assembly for hipot (dielectric withstand testing): (UL60601-1)

   - Using a Quad tech Sentry Hipot tester per the following procedure:
     Apply 1500 volts RMS. Voltage shall ramp up for 10 seconds, hold for 60 seconds, then ramp down for 0.5 seconds. During the test no flashover or breakdown shall occur. Slight corona discharges are neglected, provided that cease when the test voltage is temporarily dropped to a lower value that is greater than the reference voltage of 250 volts and provided that the discharges do not provoke a drop in test voltage
   - Arc over limit shall be set at 5mA.

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